Demonstration of Capability (DOC and PT)

ID 14749
Current Step is Close DOC Certification
Date Expires is 4/17/2019 12:00:00 AM
Initiated by Breslin Colin
Next Step by Breslin Colin on 6/15/2018 8:30:00 AM
Next Step by Breslin Colin on 6/15/2018 8:37:36 AM
Submit for Peer Review by Breslin Colin on 6/15/2018 8:45:25 AM
Approve DOC; Submit for QAC Review by Awanya Francis on 6/15/2018 9:10:50 AM
Approve DOC; Proceed to Certification Date Assignment by Ockrassa Davis Angela on 6/15/2018 3:52:37 PM
Submit DOC for DD Review by Ockrassa Davis Angela on 6/15/2018 3:53:25 PM
Approve DOC by Schupp George on 6/18/2018 8:14:30 AM
Launched Workflow Record Disposition (ID: 14763) on 6/18/2018 8:14:36 AM
Record Disposition Launched; Close DOC by Workflow Action Executor on 6/18/2018 8:14:36 AM

Close DOC Certification

DOC - DOC Certification Date (begin date)
This date should match the date of analysis or workflow submittal to QAC and it's valid for 1 year plus a month.
5/17/2018

DOC - DOC Certification Expiration Date (end date)
This date is the expiration date of the DOC certification, and it is set 1 year and 1 month from the DOC Certification Date (begin date).
6/17/2019

DOC - Workflow Expiration Date
This date should be set to 2 month before the certificate date expires. The cert date expires 1 year and 1 month after the set date.
4/17/2019

DOC - Short Title
Select the appropriate analysis (and matrix) from the list below. For field edits, including additions, contact a system admin.
AIG048A Ignitability by Setaflash

DOC - Certification
non-PT DOC (P&A, MDL, RL, etc)

DOC - Certification Type

Certification Type	If Other certification, please specify	Instrument Status	If new, list instrument name and serial number.	Comment(s)
ADOC (P&A Study)		Existing		

DOC - Certification Information
The following date (directly below) indicates when the analyst to which this DOC belongs to is granted authority to operate the listed equipment based upon final approval.

Date of Analysis (study) or Entry (historical)	Dates of Historical Analyses (if applicable)	Work Order Number(s)	Instrument ID
5/17/2018		1805012	Setaflash 3

DOC - Analysis Information

Analytical SOP and Revision Number	Analysis Name (abbreviated name)	Matrix	If Other matrix, please specify

AIG048A V5	Ignitability by Setaflash	Other	para-xylene reference material

DOC - Additional Preparation Covered by this DOC (if applicable)

DOC - Case Narrative and/or Training Checklist Attachment
14750 1805012-Flashpoint-CB.docx

DOC - DOC Summary Spreadsheet
Spreadsheet file extension should be .xlsm (if it is not, please convert it by selecting 'save as' and the desired file type)
14751 SS-AIG-P&A-RL(W)-01-3208-1.XLSM

All sample preparation, calibration, and analytical steps were done by the analyst to which this ADOC applies. (Analyst Review)
Initial ADOC only
Yes

All of the analytical steps and at least 1/2 of the sample prep & cal steps were done by the analyst to which this ADOC applies. (Analyst Review)
Continuing ADOC only
Yes

The supportive documentation for the DOC Summary Spreadsheet results has been reviewed and meets policy requirements. (Analyst Review)
Yes

All data submitted for historical data DOC were analyzed within 10 months to date of DOC submittal and at least 1/2 within 6 months. (Analyst Review)
Exception: The MDL DOC historical data meets the set 40 CFR part 136 frequency requirements.
n/a

If this is an initial ADOC (1st time performing the technology), was a training checklist completed? (Analyst Review)
n/a - not an "initial" ADOC

Are there outstanding items from the initial ADOC checklist that need to be addressed? (Analyst Review)
No

DOC - Analyst DOC Comment

Comment Date	Analyst DOC Comment
6/15/2018	Continuing ADOC for flashpoint.

DOC - Designated Peer Reviewer
Awanya Francis(540)

1. Were the data collected for MDLb and MDLs spread over at least 3 batches on 3 separate days?
Analysis and Preparation if applicable

2a. Were the data collected within the last 24 months (analysis date), and does it include the most

recent data?

2b. If data with gross failures were present and outlier(s) were removed, is the rationale for their removal documented in this workflow instance?

3. Were the data for MDLb and MDLs reviewed and evaluated to determine the final MDL?

4a. If the newly determined MDL was <0.5 or >2 of the existing MDL, was the MDL updated?

4b. If >3% of the method blank results were > the existing MDL, was the MDL updated?

5. If the MDL was calculated using data from multiple instruments, were at least 2 spikes/2 method blanks analyzed on different dates per instrument?
Applicable to MDL calculation using data from muliple instruments

6a. Were at least 2 spikes/2 method blanks analyzed on the new instrument?
Applicable to a new instrument when MDL has already been established for existing instrument(s)

6b. Were all new method blank results analyzed on the new instrument below the existing MDL?
Applicable to a new instrument when MDL has already been established for existing instrument(s)

6c. After combining new and existing spike results and recalculating the MDL, is the recalculated MDL within 0.5 to 2 times the existing MDL?
Applicable to a new instrument when MDL has already been established for existing instrument(s)

7a. [QAC] Was the response of the native concentration at a signal to noise ratio of approximately 5-20?
Applicable to MDL determination for a specific sample matrix (based on client request)

7b. [QAC] If S/N ~ 5-20, was the matrix-specific MDL determined according to 40 CFR part 136 section B but without spiking additional analyte?
Applicable to MDL determination for a specific sample matrix (based on client request)

7c. [QAC] If S/N < 5, was the analyte spiked into the sample matrix to obtain a concentration that gave results with S/N ~ 10-20?
Applicable to MDL determination for a specific sample matrix (based on client request)

DOC - MDL Summary Spreadsheet

DOC - Analyst MDL Comment

Comment Date	Analyst MDL Comment

Does the peer reviewer concur with the answers provided by the analyst to which this DOC applies regarding the DOC procedure and documentation?
Yes

DOC - Approval Comment (peer)

I approve

DOC - Return Comment (Peer)

DOC - Comment Date (peer)	DOC - Return Comment (peer)

If there were outstanding items from the initial ADOC checklist, was there a follow-up?
n/a

The supportive documentation for the DOC Summary Spreadsheet results has been reviewed and meets policy requirements. (QAC Review)
Yes

DOC - Approval Comment (QAC)
looks good

DOC - Return Comment (QAC)

DOC - Comment Date (QAC)	DOC - Return Comment (QAC)

If additional SOP preps deemed "similar" are submitted, does the Deputy Director approve their qualification under this DOC?
n/a

If there were outstanding items from the initial ADOC checklist, does the Deputy Director approve the additional documentation provided?
n/a

If this is the analyst "initial" ADOC, does the Deputy Director approve the attached training checklist documentation provided?
na - this is not an initial ADOC or see comment field

The supportive documentation for the DOC Summary Spreadsheet results has been reviewed and meets policy requirements. (DD Review)
Yes

DOC - Approval Comment (DD)
approved.

DOC - Return Comment (DD)

DOC - Comment Date (DD)	DOC - Return Comment (DD)
6/18/2018	

PT - Information per Study

Study Number	Vendor Catalogue #	Work Order	PT Transmittal Form(s)

6/18/2018

If a LIMS EDD is attached, does it meet the file format requirements stated in the pertinent work instruction? (Analyst Review)

PT - Analyst Processing Comment

Date of Analyst Processing Comment	Analyst Processing Comment

PT - Designated Peer Reviewer

If a LIMS EDD is attached, does it meet the file format requirements stated in the pertinent work instruction? (Peer Review)

PT - Approval Comment (peer)

PT - Return Comment (Peer)

PT - Comment Date (peer)	PT - Return Comment (peer)

PT - QAC Processing Comment/Request

Date of QAC Comment/Request	QAC Processing Comment/Request

PT - Date Submitted for Transmittal

PT - Date Transmitted to Provider and Uploaded to Qualtrax

PT - Accepted by Study?

PT - Evaluation Note (QAC)

Date of Evaluation Note	Evaluation Note (QAC)

PT - Latest Provider Eval Rpt (Attachment)

PT - Name of Analyte(s) Not Accepted

Date of Documentation	Name of Analyte(s) Not Accepted

PT - Failed analyte(s) tracked by QAC?
Failed analytes must be documented on the tracking spreadsheet.

PT - Responsible Party

Corrective Action Due Date

PT - Investigation Documentation

Date of Investigation	Investigation Documentation

PT - Investigation Attachment(s)

PT - Investigation Review Comment

Date of Comment	Investigation Review & Effectiveness Comment

PT - Return for Additional Investigation Info

Date of Request	Additional Investigation Info Request

PT - Study (Re-Do) Information

PT Study (Re-Do) ID and Open/Close Dates	PT Study (Re-Do) Ordered Date

PT - Approval Comment (DD)